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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,235	10/22/2001	Chandrashekhar Pathak	SBI-082	4921

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EXAMINER	
AZPURU, CARLOS A	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/991,235	PATHAK ET AL.	
	Examiner	Art Unit	
	Carlos A. Azpuru	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-62* is/are pending in the application.

4a) Of the above claim(s) *24-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-61* is/are rejected.

7)☒ Claim(s) *45-61* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the amendment filed 04/23/04.

Specification

The specification refers to poly(?-butyrolactone) at page 10, line 32. Correction is required.

It is also noted that applicant refers to the new claims as "previously presented" or "previously amended". Applicant is reminded that presentation of these new or amended claims occurred during non-responsive replies to an office action. Therefore, the are considered as newly presented in this action.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

The application contains two claims numbered 45 (see page 4, bottom; page 5, top). Correction is required.

Response to Arguments

Applicant's arguments filed 04/23/04 have been fully considered but they are not persuasive.

Applicant argues that claim 42 is allowable over the cited prior art because the claim recites a two layer coating, the first being a rapid release layer, and the second being a slow release layer. However, review of claim 42, clearly shows that no discussion is made of the release rates of the claimed layers. Indeed, only an external layer, and an adhesive layer are claimed. As to the "intermediate layer" discussed by applicant at page 7, no such layer appears in claim 42.

Applicant goes on to state that the two layer coating of the instant claims is novel and unobvious. However, EPO'721 clearly teach that multiply laminated layers may be used with different drugs found within each layer (see col. 6, lines 48-51). So that statement as to the lack of drug found in a second coating is not correct.

Applicant further states that a "slow release film is not a polymeric layer as claimed", but makes no supporting or evidentiary statements to support this argument.

Although applicant states that biodegradable external coatings are novel, EPO'721 teaches the use of biodegradable polymers in multiply coated (as well as multiply drug loaded) stent coatings at col. 5, lines 35-41.

Claim 44 sets out an adhesive layer comprising a biostable layer. This corresponds to the reinforcement layer of EPO'721, at col. 6, lines 38-48. The generic concept of an adhesive layer is further taught by EPO'721 at col. 7, lines 35-38.

Having two biologically active substances in any layer is clearly suggested by EPO'721 in claim 3 which sets out drugs for incorporation. The term "and mixtures thereof" clearly contemplates the combination of several drugs. However, it must also be noted that a review of the instant specification fails to find any support for drugs other than HMG-CoA reductases.

While applicant sets out a rapid release and slow release layers in claims 47 and 48, the statement is also made that 'the nature of the polymers in claims 47 and 48 is not known. Therefore they can not differentiate from the reference. Further, review of the specification again fails to find any support for these types of layer coatings.

The various drugs set out in claims 49-51, 55, 56, 60 and 61 are not supported by the specification are considered new matter.

With regard to applicant's statement that the "polymeric materials in claims 52 and 53 are unknown for the structure of the independent claims", clarification is requested. The EPO'721 reference clearly discusses these polymers at col. 5, lines 36-41.

In claim 54, applicant discusses a "two-phase motif". However, aside for the multiple layer coating which has already been discussed above, the limitation of having a rapid release activity for up to 90 days for the external layer, and adhesive layer with a slow release activity for greater than 90 days is unsupported by the original specification, and is considered new matter.

Claims 57 and 58 also appear to have no support in the original specification as there is no discussion of the relative thickness of the layers or multiple biostable layers.

As such, the rejection over EPO'721 is hereby maintained in view of the newly presented and amended claims.

The following rejections are cited in view of applicant's new claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42—61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a coated stent containing HMG-CoA reductase, does not reasonably provide enablement for other bioactive agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

While applicant specifically recites the HMG CoA reductases for inclusion in the stent coatings, applicants have no adequately enabled the inclusion of other bioactive agents. .The general statement made in the specification indicating the inclusion of other agents which block restenosis does not provide the ordinary practitioner with the enablement to practice the invention.

Claims 48 and 49 also lack adequate enablement for the rapid and slow release polymers claimed. No enablement exits for such a polymer coating.

Claim 57 lacks adequate enablement since the original specification does not refer to a thicker external layer.

Claim 58 lacks adequate enablement for two or more biostable layers.

Claims 49-51, 54-56, 60 and 61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 49-51, 55, 56, 60 and 61 are considered new matter since the original specification did not list any of the claimed additional bioactives.

Claim 54 is considered new matter since the original specification does not set out a stent containing both a slow release polymer coating and a rapid release polymer coating, with release activity for up to 90 days, and for greater than 90 days, respectively.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 45, 53 recites the limitation "biostable polymer" in claim 43. There is insufficient antecedent basis for this limitation in the claim.

Claim 45 refers to a “biostable adhesive layer” not found in claim 43.

Claim 53 refers to the biostable polymer of claim 43. Claim 43 refers to a biostable layer not a polymer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 42-46, 52 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over EPO'721.

EPO'721 suggests a multi-layered coating for stents at col. 7, lines 35-38. Biodegradable polymers for use in the formation of these layers is suggested at col. 5, lines 35-41. Specific polymers such as polylactide are found in this citation. EPO'721 teaches a reinforcement layer which is biostable and acts as an adhesive layer at col. 6, lines 38-48. The combination of different drugs in a layer is contemplated by applicants statement "and mixtures thereof", in claim 3. HMG CoA reductase inhibitors and other antiproliferative agents are found at (col.4, lines 49-50). Multiple biodegradable layers are taught at col. 6, lines 48-51. EPO'721 differs only in naming the inner layer an "adhesive layer". However, those of ordinary skill would have expected similar therapeutic results from the instant multiplayer stent coating given the same components for their art recognized purpose as taught by EPO'721. There are no unusual and/or

unexpected results which would rebut prima facie obviousness. The instant invention would have been obvious given the teachings of EPO'721.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Election/Restrictions

This application contains claims 24-41 which are drawn to an invention nonelected with traverse in the reply filed on 03/03/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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